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| APPLICATION NO.                                                                                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/523,219                                                                                      | 10/19/2005  | Kenneth Michlitsch   | JM-045 US           | 8323             |
| 35023                                                                                           | 7590        | 09/05/2006           | EXAMINER            |                  |
| LUCE, FORWARD, HAMILTON & SCRIPPS LLP<br>11988 EL CAMINO REAL, SUITE 200<br>SAN DIEGO, CA 92130 |             |                      | NEAL, TIMOTHY J     |                  |
|                                                                                                 |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                                                 |             |                      | 3731                |                  |

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/523,219             | MICHLITSCH, KENNETH |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Timothy J. Neal        | 3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 August 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) 27-30 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-26 and 31-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                           |                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                      | Paper No(s)/Mail Date. _____.                                               |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                                           | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Species A in the reply filed on 8/17/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-20 were previously cancelled. Claims 21-26 and 31-40 are drawn to the elected species. Claims 27-30 are drawn to non-elected species.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 21, 22, 24-26, 33, and 36-39** are rejected under 35 U.S.C. 102(b) as being anticipated by Hannam et al. (US 5,649,959).

Hannam discloses:

**21.** A device for sealing a puncture tract by forming and extruding an autologous plug within the puncture tract, wherein the puncture tract is disposed within tissue proximal to

a vessel, the device comprising: a housing having a lumen (Fig 10) adapted to mix a volume of blood with a blood congealing agent; a closure element (Fig 10 Item 30) configured to be inserted into the puncture tract and to isolate the mixture of the volume of blood and the blood congealing agent from the vessel during formation of the autologous plug from the volume of blood by action of the blood congealing agent; and a plunger (Fig 10 Item 38) disposed for translation within the lumen to extrude the autologous plug formed within the lumen.

**22.** The device of claim 1, wherein the housing comprises a second lumen to facilitate placement of a distal end of the device (Fig 11 Item 66).

**24.** The device of claim 1, wherein the autologous plug formed in the lumen has a length and a form factor that causes the autologous plug to engage tissue surrounding the puncture tract after ejection by the plunger into the puncture tract (Col 12 Line 5).

**25.** The device of claim 1, wherein the closure element comprises a pledget and thread (Fig 10 Item 30 and 36).

**26.** The device of claim 5, wherein at least one of the pledget and the thread is biodegradable (Col 7 Line 57).

**33.** The device of claim 1, wherein the blood congealing agent is introduced into the

lumen subsequent to actuation of the closure element (Col 12 Line 66-Col 13 Line 44).

**36.** The device of claim 1, wherein the blood congealing agent is chosen from the group consisting of thrombin, fibrin, human factor VIII, and combinations thereof (Col 9 Line 22).

**37.** The device of claim 1, wherein the blood congealing agent comprises a matrix (Col 8 Line 37).

**38.** The device of claim 17, wherein the matrix is chosen from the group consisting of gauze, biocompatible foam, and spun fiber (Col 8 Line 37).

**39.** The device of claim 17, wherein the matrix is biodegradable (Col 8 Line 37).

**Claims 21-26, 31, 32, and 37-40** are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (US 5,545,178).

Kensey discloses:

**21.** A device for sealing a puncture tract by forming and extruding an autologous plug within the puncture tract, wherein the puncture tract is disposed within tissue proximal to a vessel, the device comprising: a housing having a lumen (Fig 1 Item 64) adapted to mix a volume of blood with a blood congealing agent; a closure element (Fig 1 Item 38)

configured to be inserted into the puncture tract and to isolate the mixture of the volume of blood and the blood congealing agent from the vessel during formation of the autologous plug from the volume of blood by action of the blood congealing agent; and a plunger (Fig 1 Item 76) disposed for translation within the lumen to extrude the autologous plug formed within the lumen.

**22.** The device of claim 1, wherein the housing comprises a second lumen to facilitate placement of a distal end of the device (Fig 1 Item 72).

**23.** The device of claim 2, wherein the second lumen is disposed within the plunger (Fig 1 Item 72).

**24.** The device of claim 1, wherein the autologous plug formed in the lumen has a length and a form factor that causes the autologous plug to engage tissue surrounding the puncture tract after ejection by the plunger into the puncture tract (Fig 5).

**25.** The device of claim 1, wherein the closure element comprises a pledget and thread (Fig 1 Item 38 and Items 42A and 42B).

**26.** The device of claim 5, wherein at least one of the pledget and the thread is biodegradable (Col 8 Line 60 and Col 9 Line 35).

31. The device of claim 1, wherein the blood congealing agent is pre-disposed within the lumen (Fig 1 Item 36).

32. The device of claim 11, wherein the blood congealing agent is coated onto an interior surface of the lumen (Col 10 Line 2).

37. The device of claim 1, wherein the blood congealing agent comprises a matrix (Col 8 Line 25).

38. The device of claim 17, wherein the matrix is chosen from the group consisting of gauze, biocompatible foam, and spun fiber (Col 8 Line 25).

39. The device of claim 17, wherein the matrix is biodegradable (Col 8 Line 25).

40. The device of claim 17, wherein the matrix comprises at least one channel disposed therethrough (Fig 1 Item 36).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 34 and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey (US 5,545,178) in view of Greenhalgh (U.S. 6,391,037).

Kensey discloses the invention substantially as claimed as stated above. Kensey does not disclose the blood congealing agent comprises a platinum wire; the blood congealing agent comprises a thermo-resistive wire.

Greenhalgh teaches a platinum and thermo-resistive wire (Col 1 Line 52) to clot blood. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Kensey's wound sealing apparatus to include Greenhalgh's platinum and thermo-resistive wires. Such a modification would promote blood clotting.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN



ANHTUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER  
